

CLEAN BREATH TOOTH- precipitated calcium carbonate, dibasic calcium phosphate, aminocaproic acid, aluminium chlorohydroxy allantoinate paste, dentifrice

K.Boeun Pharmaceutical Co.,Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Precipitated Calcium Carbonate, Dibasic Calcium Phosphate, Aminocaproic Acid, Aluminium Chlorohydroxy Allantoinate

Water, D-Sorbitol Solution, Concentrated Glycerin, Silicon Dioxide, Sodium Cocoyl Glutamate, Polyethylene Glycol 1500, Xanthangum, Mentha Oil, Enzymatically Modified Stevia, Titanium Oxide, Sodium Chloride, Propolis Extract, l-Menthol, Xylitol, Ascorbic Acid, Green Tea Extract, Aloe Extract, Tocopherol Acetate

For dental care

Keep out of reach of children

Apply an appropriate amount to your toothbrush and brush your teeth by brushing.

Warnings

Keep out of reach of children

■ **If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.**

Other Information

■ **Store in an airtight container at room temperature**

■ **Date of use : 36 months from the date of manufacture**

For dental use only

Product name: **CLEAN BREATH TOOTHPASTE (180g)**

Drug Facts	
Active Ingredient	Purpose
Precipitated Calcium Carbonate 36.00%	Anti-Plaque
Dibasic Calcium Phosphate 0.07%	Anti-Plaque
Aminocaproic Acid 0.06%	Gum care
Aluminium Chlorohydroxy Allantoinate 0.06%	Gum care

Uses

- Aids in the prevention of dental cavities.
- Plaque removal (Anti-Plaque)

<ul style="list-style-type: none"> ■ Prevention of periodontal disease, prevention of gum disease.
<p>Warnings</p> <p>Keep out of reach of children</p> <ul style="list-style-type: none"> ■ If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.
<p>Directions</p> <ul style="list-style-type: none"> ■ Apply an appropriate amount to your toothbrush and brush your teeth by brushing.
<p>Other Information</p> <ul style="list-style-type: none"> ■ Store in an airtight container at room temperature ■ Date of use : 36 months from the date of manufacture
<p>Inactive Ingredients</p> <p>Water, D-Sorbitol Solution, Concentrated Glycerin, Silicon Dioxide, Sodium Cocoyl Glutamate, Polyethylene Glycol 1500, Xanthangum, Mentha Oil, Enzymatically Modified Stevia, Titanium Oxide, Sodium Chloride, Propolis Extract, l-Menthol, Xylitol, Ascorbic Acid, Green Tea Extract, Aloe Extract, Tocopherol Acetate</p>
<p>Questions or Comments?</p> <p>email: info@beyondi.kr</p>

[DISTRIBUTED BY]

[MANUFACTURERFOR]

[MANUFACTURERBY]

K.Boeun Pharmaceutical Co.,Ltd.

114, Jangjagyaeongje-ro, Sinbuk-myeon, Pocheon-si, Gyeonggi-do, Republic of Korea

82-31-536-7990

[PACKED BY]

CLEAN BREATH TOOTH

precipitated calcium carbonate, dibasic calcium phosphate, aminocaproic acid, aluminium chlorohydroxy allantoinate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74724-0028
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J) (CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS - UNII:L11K75P92J)	CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS	0.07 g in 100 g

CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	36 g in 100 g
ALCLOXA (UNII: 18B809DQA2) (ALCLOXA - UNII:18B809DQA2)	ALCLOXA	0.06 g in 100 g
AMINOCAPROIC ACID (UNII: U6F3787206) (AMINOCAPROIC ACID - UNII:U6F3787206)	AMINOCAPROIC ACID	0.06 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74724-0028-1	180 g in 1 TUBE; Type 0: Not a Combination Product	11/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/30/2021	

Labeler - K.Boeun Pharmaceutical Co.,Ltd. (695674074)

Registrant - K.Boeun Pharmaceutical Co.,Ltd. (695674074)

Establishment

Name	Address	ID/FEI	Business Operations
K.Boeun Pharmaceutical Co.,Ltd.		695674074	manufacture(74724-0028)

Revised: 11/2021

K.Boeun Pharmaceutical Co.,Ltd.